3524. Misbranding of radium chloride solution. U. S. v. 1 Ampul, etc. (F. D. C. No. 31311. Sample No. 13618–L.)

LIBEL FILED: July 3, 1951, District of Colorado.

ALLEGED SHIPMENT: On or about June 1, 1951, by the United States Radium Corp., from New York, N. Y.

PRODUCT: 1 unlabeled ampul of *radium chloride solution* at Denver, Colo., in the possession of the Denver Radium Corp., together with quantities of a booklet entitled "Radium Therapeutics" and folders entitled "Radium and High Blood Pressure," "New and Non Official Remedies," and "Modified Radium."

In a "Certificate of Analysis" which was sent by the shipper to the consignee, the product was represented to contain 1.06 ± .02 milligrams of radium.

RESULTS OF INVESTIGATION: After receipt, the consignee diluted the product with 40 cc. of salt solution and stored the mixture with the intention of placing it into ampuls for distribution. In addition, the consignee prepared the printed matter described above and used it in promoting the sale of the product.

NATURE OF CHARGE: Misbranding of the article before dilution, Sections 502 (b) (1) and (2), the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; Section 502 (e) (1), the label of the article failed to bear the common or usual name of the drug; and, Sections 502 (f) (1) and (2), the labeling of the article failed to bear adequate directions for use and such adequate warnings against unsafe dosage or methods or duration of administration or application in such manner and form as are necessary for the protection of users. The article before dilution was misbranded in the above respects when introduced into and while in interstate commerce.

Misbranding of the article after dilution, Section 502 (a), certain statements in the above-named booklet and folders accompanying the article were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for pernicious and secondary anemia, hypertension, myocardial affections, chronic articular and muscular rheumatism, insomnia, neuralgia, neuritis, neurasthenia, gout and similar disorders, chronic bronchial affections, gastric and duodenal ulcers, hay fever, lumbago, malnutrition, prostatitis, cystitis, sciatica, arthritis deformans, cardiovascular degeneration, endocarditis, vaginal and cervical disorders, recurrent uterus carcinoma, dysmenorrhea, fibroid tymors-sub-mucous (*sic*), nontubercular ulcers of the bladder, nephritis, urethritis, syphilis, hypertrophy of the thyroid, toxic and exophthalmic goiter, cataract (early stage), multiple sclerosis, arteriosclerosis, derangements of the circulatory, glandular, and nervous systems, Raynaud's disease, stricture, hypertrophic prostate, diseases of the kidneys and genito-urinary system, endometritis, low blood pressure evidenced by a deficiency in blood count of red corpuscles, thinness of blood and resultant low tension, chronic inflammatory conditions in general, and almost all of the ills the human body is heir to. The article was not an adequate and effective treatment for such symptoms, diseases, and conditions. The article after dilution was misbranded in the above respects while held for sale after shipment in interstate commerce.

DISPOSITION: August 22, 1951. Default decree of condemnation. The court ordered that the product be delivered to the Food and Drug Administration.